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EXAMINER
OSWECKI, J

ART UNIT	PAPER NUMBER
1613	9

DATE MAILED: 09/14/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/925,326

Applicant(s)
Lebaut et al.

Examiner
Jane Oswecki

Group Art Unit
1613



☒ Responsive to communication(s) filed on August 14, 1998 in Paper No. 8

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) 8 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☒ Claim(s) 7 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-8 are pending in the application.

Election/Restriction

Applicants' election of Group II, drawn to compounds of formulae I and II, in Paper No. 8 of August 14, 1998 is acknowledged. Because the applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)). Claim 8 has been withdrawn from consideration by the examiner under 37 C.F.R. 1.142(b) as being directed to a non-elected invention. The restriction requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

The following quotation of 35 U.S.C. 101 forms the basis for all rejections based on non-statutory subject matter found within this Office action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 4 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter since "use of" is not a recognized category of invention. As such, claims 3 and 4 have not been examined on their merits.

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Claim Rejections - 35 USC § 102(b)

The following is a quotation of 35 U.S.C. 102(b) which forms the basis for all lack of novelty rejections found withing this Office action:

“A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.”

Claims ^{and 2 are} 1 _{is} rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al., “Probing the 5-HT₃ receptor site using novel indole-3-glyoxylic acid derivatives,” Med. Chem. Res., 3(5-6), 1993, pp. 386-406. Evans et al. disclose indole-3-glyoxylic acid derivative compounds having a pyridine substituent and which are useful as serotonin receptor ligands (Evans et al., “Probing the 5-HT₃ receptor site using novel indole-3-glyoxylic acid derivatives,” Med. Chem. Res., 3(5-6), 1993, pp. 386-406; Abstract). Thus, Evans et al. anticipate the compounds of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al., "Probing the 5-HT₃ receptor site using novel indole-3-glyoxylic acid derivatives," Med. Chem. Res., 3(5-6), 1993, pp. 386-406 and U.S. Pat. 3,801,594 to Poletto et al.

The applicants claim optionally substituted indol-3-glyoxylamide derivative compounds having pyridine as a substituent in the R₁ position. These compounds have utility as immunodilator and anti-asthmatic agents.

Evans et al. teach indole-3-glyoxylic acid derivative compounds that bind 5-HT₃ receptor sites and thus are serotonergic receptor ligands (Evans et al., "Probing the 5-HT₃ receptor site using novel indole-3-glyoxylic acid derivatives," Med. Chem. Res., 3(5-6), 1993, pp. 386-406 ; Abstract). Evans et al. further teach an α -oxo-N-3-pyridinyl-1H-indole-3-acetamide compound like that of the instant application (Id.). Any further comparisons between what is taught by Evans et al. and the instant application awaits a full copy of the Evans et al. journal article.

The only difference noted between the indolyl-3-glyoxylamide derivative compounds of the instant application and those taught by Evans et al. is the greater number of possible substituents claimed in the instant application.

Poletto et al. teach optionally substituted heteroethyleneindole derivative compounds which have utility as central nervous system depressants, analgesics, diuretics and anti-inflammatories (U.S. Pat. 3,801,594, Abstract). Poletto et al. further teach optionally substituted 5-methoxyindole-3-glyoxylamide derivative compounds that may have an "R₁" substituent that is

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pyridine (U.S. Pat. 3,801,594 at column 8, Table II, lines 10-63 and especially lines 10-20 and 46-49).

The difference between the compounds of the instant application and those taught by Poletto et al. is that the "R₁" substituent of Poletto et al. is bonded directly to one of the two "C=O" moieties rather than to a nitrogen atom.

Thus, it would have been obvious to one skilled in the art of glyoxylamide derivative compounds to have utilized the optional substituents as taught by Poletto et al. on the indolyl-3-glyoxylamide derivative compounds having a pyridine substituent as taught by Evans et al. A skilled artisan would have been motivated to do so in order to prepare additional anti-asthmatic and immunodilatory compounds.

Claim Rejections - 35 USC § 112, First Paragraph

The following quotation of 35 U.S.C. 112, first paragraph, forms the basis for all rejections based on lack of enablement found within this Office action:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

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Claims 1, 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some “unnatural amino acids” and “customary excipients and/or diluents or auxiliaries”, does not reasonably provide enablement for all unnatural amino acids, excipients, diluents or auxiliaries. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, certain factors must be considered under the holding in In re Wands, 8 U.S.P.Q.2d 1400, 1404 (CAFC, 1988): 1) the nature of the invention which is directed to indolyl-glyoxylamide derivative compounds which have pharmaceutical activity; 2) the state of the prior art is that such compounds are known and are known to have pharmaceutical activity; 3) the claims are of such breadth as to include all unnatural amino acids, customary pharmaceutical excipients and/or diluents or other auxiliaries as part of the pharmaceutical compositions; 4) the level of ordinary skill in the art is high and requires specialized training beyond a baccalaureate level; 5) the level of predictability within the art is low as is true of chemical and biological systems; 6) no direction is provided by the inventors for what they intend as unnatural amino acids, customary pharmaceutical excipients and/or diluents or other auxiliaries; 7) there are no working examples of unnatural amino acids or pharmaceutical compositions that include diluents, excipients or auxiliaries given by the inventors; 8) thus, an undue quantity of experimentation is needed to make invention based on the content of the disclosure.

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35 U.S.C. 112, Second Paragraph

The following quotation of 35 U.S.C. 112, second paragraph, forms the basis for all lack of clarity rejections found within this Office action:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 1, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the term “unnatural amino acid” at line 32 on page 28 renders the claim unclear.

Also, regarding claim 1, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, because it is unclear what the applicants intend for excipients, diluents and auxiliaries to be used with indolyl-3-glyoxylamide derivative compounds in pharmaceutical compositions.

Appropriate corrections are required in all instances.

Claim Objections

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Claims 1 and 6 are objected to because of the following informalities: claim 1 is written in inappropriate format because it contains more than one sentence and includes the bracketed “[sic]” at page 27, lines 17 (see 37 C.F.R. 1.75). In addition, corrected spelling of the word “pyridine” at line 28 on page 27 and in all other occurrences is required; replacement of the terms “...can be...” with the more definite “...may be...” at page 28, lines 16, 21 and 31 and in all other occurrences also is required. Further, it is requested that all unnecessary parentheses be removed from claim 1 as on page 29, lines 6 and 7, and in all other occurrences, and that definitional phrases such as appear on page 30, lines 25ff, of claim 1 be deleted from the claim.

Claim 6 is objected to for including the phrase, “...characterized in that...”. Claim 6 would be acceptable if the word “wherein” replaced the phrase, “characterized in that...”.

Claim 7 is objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required in all instances.

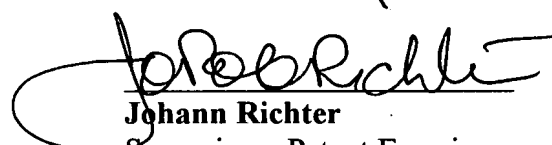
Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Oswecki whose telephone number is (703)305-7152. The examiner can normally be reached Monday through Thursday from 7:30 AM to 5:30 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at (703)308-4532. The telephone number for this Group is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-1235.



Johann Richter
Supervisory Patent Examiner
Group 1600

JCO
September 14, 1998